Drug Importation: Would the Price Be Right?
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Testimony

Thank you, Mr. Chairman and distinguished members of this committee, for this opportunity to offer my perspective on the now-prominent issues of pharmaceutical importation, domestic/foreign pricing differentials, and the long-term economic effects of pharmaceutical price controls and federal price negotiations, particularly in the context of consumer well-being.

Well-known principles of economic analysis and existing bodies of data not subject to serious challenge yield several conclusions on the prospective adverse effects of the importation of price-controlled pharmaceuticals into the U.S. Moreover, the recent "free-market" argument favoring the importation of price-controlled pharmaceuticals is deeply flawed, as discussed below. Similarly, the perverse market effects of a possible imposition of federal negotiating power---federal "interference"---in the context of the Medicare program are not difficult to predict. Alternatively, U.S. consumers would benefit from efforts to end the free ride that foreign consumers are able to obtain on U.S. research and development investments, financed largely by U.S. consumers. These central observations and some other ancillary arguments form the basis of my testimony today.

I. Pharmaceuticals Subject to Price Controls Overseas Are Not "Cheap."

The true economic cost of pharmaceuticals---that is, the real resource cost to the economy of developing and producing them---cannot be reduced without improvements in the economic and regulatory environment, a broad set of issues outside the scope of today's hearing. The importation of drugs subject to foreign price controls, far from reducing real economic costs, by necessity would import those price controls into the U.S. in terms of prices received by manufacturers. To the extent that lower prices for consumers result, that would not represent a true reduction in "costs"; instead it would be a wealth transfer from pharmaceutical producers and possibly from foreign consumers to U.S. consumers in the short run, with adverse consequences for U.S. consumers in long run, as discussed below. The more likely short run outcome for U.S. consumers, depending on market conditions, would be little or no price reductions but instead price increases for various market participants (intermediaries) in the supply chain, since the importation of price-controlled pharmaceuticals would not affect either market demand conditions or market supply conditions on the margin.

In the long run---which is not necessarily a long period of time---it is incontrovertible that

lower prices will reduce the marginal efficiency of investment, that is, the incentive to invest in the research and development of new pharmaceuticals. Since ultimately it is anticipated consumer demands---for cures, for disease alleviation, for better health, and for reduced suffering---that drive the research and development choices of profit-seeking firms, lower anticipated prices will reduce research and development investment and thus the future flow of new drugs. The adverse future effects in terms of fewer cures and greater suffering will be real economic costs attendant upon the importation of foreign price controls; but such costs will not appear directly in government budgets or private balance sheets, except to the (significant) extent that more-costly hospitalizations and other substitute medical procedures will be used in place of the drugs that will have failed to have been developed due to the long term effects of price controls. Thus will the adoption of price controls through the vehicle of the importation of price-controlled drugs mortgage the future in favor of the present by weakening incentives for research and development investment and other activities yielding streams of new and improved medicines.

Based upon the recent experience in the non-U.S. OECD and upon simulation exercises and other analyses, the magnitude of this projected adverse research and development effect varies somewhat, although it is never predicted to be small. My view is that all of these estimates are biased downward because they fail to take into account the fact that the imposition of price controls, whether direct or indirect, introduces an asymmetry into the statistical distribution of future returns to research and development, in that the price controls have the effect of limiting (truncating) upside potential while leaving downside risk unaffected. This is an effect separate from the price reduction itself, the implication of which is that the long term effects of price controls in terms of a reduced flow of new and improved drugs is likely to prove larger rather than smaller.

Some observers have argued that there can be an inefficiently large amount of pharmaceutical research and development investment, so that a reduced amount still may be efficient. High purported “profits” (either undefined or defined poorly) then are used to infer that current investment is too high. But if “profits” are (uncompetitively) high---adjusting for investment risk---we would expect to see significant entry into the market by new firms. We do not.

More generally, the current emphasis by some commentators on total revenues or total profits as predictors of research and development incentives is incorrect. It is the marginal efficiency of investment for a particular research and development effort that is relevant. Consider, for example, a firm earning enormous profits, however defined; would it sink dollars into a project that it knows will not yield adequate returns (however broadly defined)? Regardless of overall revenues or profitability, firms have powerful incentives to make only efficient investments, that is, investments expected to yield at least normal rates of return with some allowance for risk. Price controls cannot further that outcome; and competitive capital markets will enforce such discipline.

Finally, an accounting of the true cost of imported drugs subject to price controls must include some consideration of the safety problem, important socially in particular in the

context of contagious diseases. That solutions to the safety problem are likely to prove highly elusive is evidenced by the fact that current legislation under discussion either shunts the issue aside completely, or apparently bestows an "FDA-approved" imprimatur upon foreign plants not actually approved by the FDA. The safety problem is discussed in detail in the Department of Health and Human Services study noted above; I will not repeat its findings here.

In short: As much as we want our medicines to be affordable, we also want them to be available when needed.

II. U.S. Consumers Would Benefit From Policies Reducing the Foreign Free Ride.

The basic cost economics of pharmaceuticals are somewhat unique, in that large fixed costs (for research, development, and production facilities) are accompanied by small marginal production costs. The large fixed costs---over $800 million per drug ---yield a body of knowledge, which itself is a classic collective (or "public") good in that those who can find ways to avoid paying their "fair" share thus obtain a free ride on the efforts of others to finance the research and development investment. Foreign price controls on drugs have the effect of yielding for foreign consumers just such a free ride at the expense of U.S. consumers.

Some have argued that policies designed to increase foreign prices would not yield benefits for U.S. consumers because "drug companies are under no obligation to lower US prices as [foreign] prices increase."

That argument is incorrect, regardless of the assumption one makes about the competitiveness of the U.S. pharmaceutical market. From the viewpoint of U.S. pharmaceutical producers, an increase in foreign prices analytically is equivalent to an increase in foreign demand; total perceived worldwide demand would increase, yielding an increase in the marginal efficiency of research and development investment, and so a long run increase in that investment and in the flow of new drugs. But, ceteris paribus, U.S. demand would not change, so that the increased long run supply of drugs would induce profit-seeking U.S. firms to reduce their U.S. prices, that is, would put downward pressure on U.S. prices. Again: This is true whether the U.S. market is viewed as perfectly competitive or as a perfectly discriminating monopoly. In the short run, it is unclear whether U.S. prices would fall; demand and cost conditions would not change, but producers might have incentives to cut prices in the expectation of increased competition over the longer term.

III. The "Free-Market Argument Favoring Drug Importation Is Fundamentally Flawed.

Some prominent supporters of free markets have argued recently in favor of the importation of price-controlled drugs. The argument in summary is that an end to the

import ban would force pharmaceutical producers to negotiate more stringently with foreign governments over the prices for drugs, because the prospect of “cheap” foreign drugs flooding the U.S. market would make it difficult to preserve U.S. prices sufficient to cover high R&D costs. The producers also could insist upon “no foreign resale” provisions in contracts, which could be enforced by limiting sales to the foreign governments.

This argument is fundamentally flawed. Most foreign governments under their patent laws reserve the right to engage in compulsory licensing under various conditions, one of which is a “failure to work the patent.” The precise meaning of that phrase is unclear, but to foreign officials it might mean a failure to sell all that is demanded at the controlled price. What is clear is that foreigners will not be happy to pay more for medicine. And so it is unlikely that foreigners faced with substantial increases in their drug costs would be fastidious in their adherence to the rule of patent or international trade law, as interpreted by U.S. drug producers and some U.S. officials. Indeed, compulsory licensing already has been used, so that price negotiations and trade environments are highly vulnerable even to implicit threats of patent theft.

Moreover, under some prominent interpretations of patent law, producers control their patents but not the resale of their patented products. Would contracts to limit resale of price-controlled drugs, even if they could be negotiated and enforced, survive challenge under this interpretation? Such uncertainties inevitably will force the producers to sign agreements eroding their ability to recover R&D costs or to protect their intellectual property.

The basic problem with the “free market” position in support of drug importation is that it tries to reconcile free markets domestically with price controls overseas. That is a circle that cannot be squared as long as foreign governments can steal patents; and in the final analysis, it is likely to be difficult and time-consuming to stop a government intent on doing so. What is needed instead are U.S. government efforts, perhaps in the context of trade policy, designed to end the free ride that many foreigners now obtain at the expense of U.S. consumers. That many U.S. officials now attack drug producers---whose investments have saved millions of lives---rather than the foreign theft of U.S. intellectual property is unlikely to prove salutary.

IV. Federal Price Negotiation Would Not Serve the Interests of Consumers.

Consider a large pharmacy chain or other sizeable intermediary between pharmaceutical producers and consumers. That intermediary must balance two competing objectives, which actually are the objectives of its customers. It seeks to reduce costs, and thus prices for its customers; and it seeks to preserve a formulary broader rather than narrower, so that it can serve as broad a market as possible, that is, preserve more rather than less consumer choice. Both objectives are driven by competition among pharmacies and other intermediaries; that these objectives conflict is obvious, so that private sector intermediaries, reflecting the preferences of their customers, must find ways to balance

them.

The more obvious difference between such private sector intermediaries and the federal government is the sheer size of the latter as a purchaser; it is almost axiomatic that the federal government has more monopsony power than private sector intermediaries. At a more subtle level, the federal government has incentives in terms of the cost/ formulary tradeoff incentives that differ substantially from those constraining private sector intermediaries. Budget pressures are strong at all times, so that incentives to negotiate substantial price reductions are powerful. But the federal government is not a profit-seeking firm, so that its incentives to satisfy its "customers" in terms of broad formularies must be attenuated through political processes; voting is simply a weaker constraint than the ability of customers to take their business elsewhere. This is a common problem with public sector services: The tradeoff incentives between cost (budget) reduction and preservation of service quality systematically are different from those constraining private sector choices. This bias in favor of price reductions as opposed to formulary availability is obvious overseas, and arguably has affected U.S. consumers in the vaccine market.

V. Conclusions.

The interests of consumers are served by a pharmaceutical sector offering medicines both affordable and available. More generally, consumers are served by economic efficiency, that is, policies yielding an aggregate output basket as valuable as possible. Policies that bestow benefits upon one set of consumers at the expense of others, perhaps in the future, are inconsistent with that goal; in particular, price controls are fundamentally incompatible with the operation of free or competitive markets, with the institutions of free trade, and with the interests of consumers. It is incontrovertible that the importation of pharmaceuticals subject to foreign price controls will have the effect of importing the price controls themselves, with clear and substantial adverse effects over the long term in terms of research and development incentives and the flow of new and improved medicines. Other analyses suggest that such policies will not save much even in the narrow dimension of budget dollars and drug spending; and the longer term costs in terms of substitution of costly substitute medical procedures and reduced human health outcomes are obvious. This committee would be wise to reject efforts to allow the importation of pharmaceuticals subject to foreign price controls.

Instead, the pursuit of consumer wellbeing would be served by policies---perhaps in the context of trade negotiations---ending the free ride that foreign governments have garnered for themselves, through the imposition of price controls, at the expense of the U.S. market. Noninterference---a farsighted policy incorporated into the 2003 Medicare legislation---with competitive private sector negotiations will further those consumer interests as well.